

16 14
15 13
53. (New) The apparatus of claim 52, wherein said angle is between about 50-90 degrees.

17 15
16 14
54. (New) The apparatus of claim 53, wherein said angle is about 70 degrees.

REMARKS

At the outset, Applicants thank the Examiner for the indication of allowability of claims 4 and 5.

The drawings have been objected to because the reference numeral "90" has been used to designate two different features. By the above amendment, the specification has been amended to correct this clerical oversight. Filed herewith, under separate cover to the draftsman, is a request for approval of drawing changes, modifying Figs. 5 and 7 to conform to the amendment. Applicant kindly requests the drawing objection be withdrawn.

Claims 6, 10, 11 and 16 are rejected under 35 USC §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to make and/or use the invention. Applicant submits that the issue is not one of enablement, but one of clarity. The second foot of claims 6, 10, 11 and 16 is not additive, but interchangeable with the first foot.

By the above amendments, claims 6, 10, and 16 are cancelled, and claim 11 amended to remove reference to a second foot, without disclaimer or prejudice. The subject matter therein has been reintroduced as new claims 49-54, in order to more clearly define the alternative nature of the embodiments of each foot. No new matter has been added. New claims 49-54 are readable on the previously elected species.

Accordingly, Applicants respectfully submit the rejection under 35 USC § 112, first paragraph, is overcome, and request the withdrawal thereof.

Claims 4 and 10 are rejected under 35 U.S.C. § 112, second paragraph, for indefiniteness relating to inadequate antecedent basis for certain limitations. By the above amendments to both claim 4 and claim 10, Applicants submit that the defects have been cured. Thus, the rejection under 35 USC § 112, second paragraph has been obviated. Applicants respectfully request withdrawal of the rejection.

Claims 1-3 and 17-19 are rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 5,976,080 to Farascioni. Applicant respectfully traverses the rejection, for at least the following reasons.

Calling attention to Figs. 36-40, claim 1 of the instant application defines an apparatus for stabilizing an epicardial surface of the heart, said apparatus comprising a foot having a first arm and a second arm, with a space between the first and second arms. Each arm has a proximal end and distal end and ***a length defined between the proximal ends and the distal ends***, the length of the first arm being longer than the length of the second arm. The measure of arm length is expressly stated, and it is unambiguous.

In contrast, Farascioni defines an instrument having supporting legs 104a and 104b, which are not disclosed to have differing lengths between a proximal end and a distal end. As can be clearly seen in Fig. 16 and others, the length between the proximal end and the distal end of each leg is identical, notwithstanding either leg's length along its own axis. "A prior art reference anticipates a claim only if the reference discloses, either expressly or inherently, every limitation of the claim." *Rowe v. Dror*, 112 F. 3d 473, 42 USPQ2d 1550 (Fed. Cir. 1997). The cited art does not anticipate the claimed invention.

Further, nowhere does Farascioni disclose that the first arm be at least 30% longer than the second arm, as recited in claim 2. Moreover, Farascioni does not disclose a

contact surface generally lying in a plane as recited in claim 3. In contrast, the instrument disclosed by Farascioni has downward protrusions (108a, 108b). Further, Farascioni does not include lateral sides which taper away from the plane, as recited in claim 3.

With respect to claims 17-19, the Examiner asserts that "the method steps, as set forth would have been inherently carried out in the operation of the device[.]" It has been illustrated above that the Farascioni device cannot anticipate the present claims. Therefore, the assertion that the claimed method is inherent based upon the apparatus cannot be sustained.

However, on their merits, claims 17-19 are clearly distinguished from Farascioni as presently constituted. As recited in claim 17, and disclosed at p. 19, lines 19-29 of the specification, the longer arm of the present apparatus is used to retract the apex of the heart during anastomosis to improve access and/or visualization. Farascioni neither discloses nor suggests this step in performing an anastomosis. The additional length of one arm over the other in the present apparatus is employed to perform this step. By its structure, the device of Farascioni cannot perform this function.

With respect to claim 19, the instrument disclosed by Farascioni does not include a foot that is detachably coupled to the shaft, as required by the claim. The foot of Farascioni is integral to the shaft, and the description offers no disclosure or suggestion of interchanging the foot while in use.

Further, the Examiner has not met the burden required to establish a *prima facie* case of inherency. "In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic **necessarily** flows from the teachings of the applied prior art." *Ex parte Levy*, 17 USPQ2d 1461, 1464 (BPAI 1990) (emphasis in original). No such basis has been provided on this record.

Claims 7-16 are rejected under 35 USC §102(e) as anticipated by U.S. Patent No. 6,152,874 to Looney, et al. Applicant respectfully traverses the rejection, for at least the following reasons.

By the above amendment, claim 7 has been cancelled without prejudice and claim 8 amended from dependent to independent form. Claim 8 includes the recitation that the arm is attached to the foot along a lateral side, and at a location offset from the axis of the slot.

In contrast to Looney, each and every embodiment discloses a handle (40) coupled to a bifurcated member (20, 22) along the axis of the slot, rather than offset from it. See Figs. 1, 12, 14, 15, 19, and 20.

With respect to claim 9, Looney does not disclose a coupling for detachably connecting the foot to the arm. As clearly seen in Figs. 1, 12, 14, 15, and 16, the bifurcated member of Looney is integral to the handle, and even requires such for proper operation. Looney does not disclose or suggest the claimed feature. On the contrary, the bifurcated member of Looney must be integrally connected with the handle for actuation by the actuator rod (35).

Claim 12 has been cancelled without prejudice and claim 13 amended from dependent to independent form. Claim 13 includes the recitation that the first foot is generally convex when viewed along a central axis defined by the slot. As disclosed in the specification, and illustrated by Figs. 38, and 41, the foot of the instant invention has a generally convex shape to provide improved access and/or visualization. The term "generally convex" is used to define the lateral surfaces that together form one generally continuous curvature. This is in contrast to Looney, which discloses prongs 22 that are cylindrical or flat bottomed, particularly when viewed along the axis on the slot. See Figs. 4, 6, 7, 20, 22, and 23.

Similarly, with respect to claims 14, now dependent from claim 13 by the above amendment, Looney does not disclose or suggest lateral surfaces which taper away from the contact surface, nor any such lateral taper angle, as recited in claim 15. Accordingly, the Examiner's rejections under 35 USC § 102(e) have been obviated. Applicants respectfully request withdrawal of the rejections.

In light of the foregoing, Applicant respectfully submits that the claims define patentable subject matter, and kindly solicits an early indication of allowability of all pending claims.

Respectfully Submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION

Please replace the paragraph on page 11, line 16 with the following paragraph:

Returning to Figure 1, the system of the invention further includes a stabilizer 70 for stabilizing the surface of the heart or other organ during a surgical procedure. Stabilizer 70 may be mounted either to rails 28, 29 or to crossbeam 22 by means of a mounting base 72. As shown more clearly in Figures 5-8, stabilizer 70 includes a shaft 74 having a distal end 76 and a proximal end 78. A foot 80 is pivotably mounted to distal end 76 by means of a ball joint 82. Foot 80 is configured to engage the surface of the heart on opposing sides of an anastomosis site, preferably having a pair of arms 84 generally parallel to each other and spaced apart by a distance in the range of about 1-5 cm. Arms 84 have a generally flat portion 86 for engaging the heart, an angled portion 88 sloping upwardly from flat portion 86, and a proximal portion [90] 91 which connects arms 84 and may have a curved, angled, or other suitable shape for attachment to a stem 92 coupled to ball joint 82. the bottom surfaces of arms 84 are adapted for atraumatic engagement with the epicardium, usually being smooth and flat. In a preferred embodiment, a friction-enhancing element is disposed on the bottom surfaces of flat portions 86. For example, the bottom surfaces may be textured with grooves, ribs, knurling, projections or other features, or they may be coated or covered with a friction-enhancing material such as foam, [Dacron] DACRON gauze, no-slip material, or a roughened or textured metal or plastic plate. Such material will enhance friction with the epicardium sufficiently to prevent slippage and migration of the foot, but not to such an extent as to injure the epicardial tissue.

IN THE CLAIMS

4. (Amended) [Apparatus] An apparatus for stabilizing an epicardial surface of the heart comprising:

an arm; and

a [first] foot coupled to the arm, the foot having a contact surface for engaging the heart and a slot in which a vessel on the heart may be positioned, the slot being aligned with a central axis, the foot having a shape which is asymmetrical relative to the central axis.

8. (Amended) [The apparatus of claim 7, wherein:] An apparatus for stabilizing an epicardial surface of the heart comprising:

an arm;

a foot coupled to the arm, the foot having a contact surface for engaging the heart, and a slot in which a vessel on the heart may be positioned, the slot defining an axis, wherein the foot is attached to the arm at a location offset from the axis, said [the] foot [has] having a lateral side; and

[the] said arm is attached to the foot along the lateral side.

9. (Amended) [Apparatus] An apparatus for stabilizing an epicardial surface of the heart comprising:

an arm; and

a foot having a contact surface for engaging the epicardial surface; and a coupling for detachably connecting the foot to the arm.

11. (Amended) The apparatus of claim 9, wherein[:]

the [first and second feet have connectors] foot has a connector which detachably engages the arm [the connectors for the first and second feet being positioned on opposite sides].

13. (Amended) An apparatus for stabilizing an epicardial surface of the heart comprising:

an arm;

a foot including a bottom surface having a contact surface for engaging the heart, a slot in which a vessel on the heart may be positioned, wherein at least a portion of the bottom surface is convex; and

the [first] foot is generally convex when viewed along a central axis defined by the slot.

14. (Amended) The apparatus of claim [12] 13 wherein:

the bottom surface has lateral surfaces which taper away from the contact surface.